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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/963,656	11/03/1997	CRAIG J. GERARD	LKS9405A2Z	1351

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EXAMINER	
MURPHY, JOSEPH F	
ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 10/08/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/963,656	GERARD ET AL.	
	Examiner	Art Unit	
	Joseph F Murphy	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 August 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *151-307* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *300-302* is/are allowed.

6)☒ Claim(s) *151-299 and 303-307* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *26* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Sequence Comparison A,B,C* .

DETAILED ACTION

Formal Matters

Claims 29, 29, 49-51, 53, 55 and 57-150 were cancelled and new claims 151-307 were added in Paper No. 26, 8/2/2002. Claims 151-307 are pending and under consideration.

Response to Amendment

The outstanding rejections have been rendered moot by cancellation of the claims.

Rejections applied to the new claims, and new issues, are set forth below.

Claim Rejections - 35 USC § 112 second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 151-307 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 151-154, 157, 163, 165, 169, 175-176, 179, 185, 188, 195, 198, 204-205, 207, 213, 217, 221-224, 227, 230, 234-239, 242, 246, 247, 250, 253, 257, 258, 263, 267-270, 273, 276 280, 282, 283, 288, 292, 296 are indefinite in the recitation of the term "naturally occurring". It is unclear whether this term imposes a required limitation on the claim, such that it only encompasses, for example, antibodies to polypeptides isolated from cells harvested from mammals, or whether it also encompasses e.g. antibodies to recombinantly produced proteins. Therefore, the metes and bounds of the claims are unclear. The dependent claims are rejected

due to their dependence on the recitation of the term "naturally-occurring" in the indicated claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 151-154, 156-166, 168-176, 178-195, 197-224, 226-247, 249-270, 272-299, 303-307 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 94/11504 (Horuk et al.) in view of U.S. Patent No. 5,530,101 (Queen et al.).

Horuk et al. teaches the cloning and expression of the C-C chemokine receptor (CKR-1) ('504 at 2). Horuk et al. teaches polyclonal antibodies to CKR-1 on page 39. Horuk et al. teaches monoclonal antibodies on page 40, as well as hybridoma production. Also disclosed are antibodies which antagonize CKR-1 activity or binding. The antibodies which bind CKR-1 would bind the amino acid sequence set forth in the instant application as SEQ ID NO: 4 (See

Sequence Comparison A, attached) as well as to the amino acid sequence set forth in the instant application as SEQ ID NO: 6 (see Sequence Comparison B, attached). It would be an expected property of antibodies to CKR-1 to compete with antibodies to the amino acid sequence set forth as SEQ ID NO: 4 or 6, because they would be competing for the same binding site. The polynucleotide which encodes CKR-1 would hybridize under the conditions listed in the relevant claims to the nucleic acid of SEQ ID NO: 3 or 5. The CKR-1 polypeptide binds RANTES, and other C-C ligands. Horuk et al. does not teach humanized antibodies, chimeric antibodies or antigen-binding fragments.

U.S. Patent No. 5,530,101 teaches methods for preparing humanized immunoglobulin chains having generally one or more complementarity determiningregions (CDR's) from a donor immunoglobulin and a framework region from a human immunoglobulin. (column 2, lines 35-40). The '101 patent also teaches the immunoglobulins, including binding fragments and other immunoglobulin forms, of the present invention may be produced readily by a variety of recombinant DNA or other techniques. Preferably, polynucleotides encoding the desired amino acid sequences are produced synthetically and by joining appropriate nucleic acid sequences, with ultimate expression in transfected cells (column 3, lines 43-50). Thus, it would have been obvious to one of skill in the art at the time the invention was made to produce humanized or chimeric antibodies to the CKR-1 polypeptide, which would also bind the polypeptides disclosed as SEQ ID NO: 4 and 6. The motivation is provided in the '101 patent which discloses that there is a need for improved forms of human-like immunoglobulins specific for a predetermined antigen that are substantially non-immunogenic in humans, yet easily and economically produced in a manner suitable for therapeutic formulation and other uses (column 2 lines 25-32).

Claims 151, 155, 157-162, 167, 175-177, 179-184, 194-196, 198-203, 212-216, 221-225, 228-223, 238-241, 246-248, 250-256, 259-262, 267-271, 273-279, 284-287, 292-295, 303-307 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,707,815 (Charo et al.) in view of U.S. Patent No. 5,530,101 (Queen et al.).

The '815 patent discloses human chemokine receptor proteins MCP-1RA and MCP-1RB, which are substantially free from other mammalian proteins with which they are typically found in their native state (column 3, lines 10-15). Also disclosed are antibodies to MCP-1RA and MCP-1RB (column 16, lines 15-18). The antibodies to MCP-1RA or B would bind the amino acid sequence set forth as SEQ ID NO: 2 in the instant application (see Sequence Comparison C, attached). The polynucleotide which encodes MCP-1RA or B would hybridize under the conditions listed in the relevant claims to the nucleic acid of SEQ ID NO: 3. The 815 patent does not teach humanized antibodies, chimeric antibodies or antigen-binding fragments.

U.S. Patent No. 5,530,101 teaches methods for preparing humanized immunoglobulin chains having generally one or more complementarity determiningregions (CDR's) from a donor immunoglobulin and a framework region from a human immunoglobulin. (column 2, lines 35-40). The '101 patent also teaches the immunoglobulins, including binding fragments and other immunoglobulin forms, of the present invention may be produced readily by a variety of recombinant DNA or other techniques. Preferably, polynucleotides encoding the desired amino acid sequences are produced synthetically and by joining appropriate nucleic acid sequences, with ultimate expression in transfected cells (column 3, lines 43-50). Thus, it would have been obvious to one of skill in the art at the time the invention was made to produce humanized or chimeric antibodies to the MCP1RA or B polypeptide which would also bind the polypeptide

disclosed as SEQ ID NO: 2. The motivation is provided in the '101 patent which discloses that there is a need for improved forms of human-like immunoglobulins specific for a predetermined antigen that are substantially non-immunogenic in humans, yet easily and economically produced in a manner suitable for therapeutic formulation and other uses (column 2 lines 25-32).

Conclusion

Claims 151-299, 303-307 are rejected.

Claims 300-302 are allowable.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph F. Murphy whose telephone number is 703-305-7245. The examiner can normally be reached on M-F 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 703-308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Joseph F. Murphy, Ph. D.
Patent Examiner
Art Unit 1646
October 7, 2002